Human experimentation and informed consent

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In a recent survey of 300 medical doctors, 81% claimed that they encountered a variety of ethical problems.[1] Simultaneously, most admitted to being ignorant of the ethical codes that govern their work. It is therefore to be expected that the concept of informed consent would be unknown or at least much misunderstood within the medical community.

The doctrine of informed consent requires the physician to make certain disclosures in lay language to their patients before subjecting them to any potentially risky procedures.[2] These are:

- a description of the proposed treatment;
- alternatives to the proposed treatment;
- problems of recuperation that are anticipated;
- inherent risks of death or serious bodily injury in the proposed treatment;
- any additional information other physicians would disclose in similar circumstances.

As with any legal rule, there are exceptions. Thus, the physician need not generally disclose the above listed information

- in an emergency;
- if the patient does not want to be informed;
- if the procedure is simple, and the danger remote and commonly appreciated as remote; and
- if in the physician's judgement, it is not in the patient's best interest to know, e.g. when the information would so seriously upset the patient that he could not rationally make a decision.

The voluntary consent of the human subject is absolutely essential. This, the first sentence of the Nurenberg code (1947), highlights the central concept of the consent requirement in research using human subjects.[3] Before 1947, statements of medical and other professional organizations made no mention of the necessity for consent. According to the Nurenberg code, to consent to participate in research one must: (a) have a "legal capacity" to give consent, (b) be so situated as to be able to exercise free power of choice (c) have sufficient knowledge on which to decide, and (d) have sufficient comprehension to make an enlightened decision.

Traditional arguments against the patient having a major role in the decision-making process are that the patient will never be able to comprehend the information related; and that the information will unduly frighten the patient, and he will therefore not consent to a procedure that actually entails only a minimal risk.

Nevertheless, it is the physician's duty to attempt to inform and educate the patient sufficiently to enable him to make up his own mind. If a physician argues this is not possible, he may in fact be saying one of two things: he cannot properly explain the risks and alternatives because he does not understand them himself, or he believes that if he does properly explain them, the patient will not understand and may become confused and frightened by the explanation, thereby decreasing the likelihood of obtaining consent.

A striking example which serves to support the need for informed consent and illustrates some of the problems which may arise out of its neglect is that of the so called "brainwashing" experiments conducted in the late 1950s at McGill University's Allan Memorial Institute (AMI).

Following the Korean war, in which the communists reportedly used brainwashing techniques on American prisoners of war with surprising success, the Central Intelligence Agency (CIA) turned its attention toward financing research in an attempt to develop similar techniques. The late Dr. D. Ewen Cameron, sometimes called the godfather of Canadian psychiatry, and the director of the AMI from its founding in 1943 until his retirement in 1964, was the recipient of over $60 000 in CIA-provided funds through a front organization called The Society for the Investigation of Human Ecology.[4] Over a period roughly spanning 1957–1960, more than 50 Canadian inpatients at the AMI were enrolled without their consent in experiments which have led some people like US investigative reporter John Marks, to call Cameron, "the closest I've come to a real life version of the archetypal mad scientist".[5]

Although the patients thought that they were being treated for their ailments which varied from obsessive-compulsive neuroses to major depression, they were, according to John Marks[4] and the editors of the Montreal *Gazette*,[6] used in brainwashing research sponsored by the CIA. Under Cameron's supervision, patients were given strong sedatives to make them sleep round the clock, except when wakened 2 or 3 times a day for electroshock treatments involving voltages 20 to 40 times above that normally used by North American psychiatrists. This procedure was continued through several stages until the patient experienced memory loss. After this depatterning, which supposedly wiped the patient's mind clean, came the psychic driving, whereby attempts were made to implant new behavioural patterns through the playing of tape recorded cue statements selected from the patients own conversations. Running on a continuous loop, the messages were played 16 hours daily for several weeks.

While some cast Cameron in a dark light, performing experiments on human guinea pigs, others prefer to label him an innovative psychiatrist who conducted experiments to help his patients overcome their self-destructive moods and behaviour.

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For example, Dr. Brian Robertson, the present director of the AMI, and Dr. James Farquhar, a resident psychiatrist at the AMI, point out that Cameron established an open-door policy at the AMI in contrast to the locked doors and wards of other mental institutions of that time. They claim also that he "worked tirelessly to restore to psychiatric patients their rights and their dignity".[7]

Dr. Heinz Lehmann, currently professor emeritus of McGill's Department of Psychiatry, himself introduced antipsychotic drugs to patients at the Douglas Hospital in 1953. According to Lehmann, "there was nothing unusual about not getting consent in those days".[8] Furthermore, because Lehmann didn't have to seek permission from anyone to give these new drugs, he completed his pioneering work in 3 months instead of the 4 or 5 years it would take him today. To Lehmann, Cameron's work "made some sense", and "It was considered acceptable in the context of the knowledge we had of the neurological science. I can't believe he treated patients who didn't need it. The people were very sick in order to get admitted to the Allan."

According to Donald Hebb, head of McGill's Department of Psychology during the period of Dr. Cameron's "reign", "If you have a certain theoretical approach, what Cameron was doing was not nearly as bad as it looks today."

While medical and scientific colleagues of Dr. Cameron are willing to grant the scientific validity of his studies and his essentially humanistic and therapeutic aims, patients have and are claiming compensation from a treatment about whose aggressive nature they were not informed while seeking and paying for proven medical care. For example, Velma Orlikow, one such patient, received $50 000 in 1981 in an out-of-court settlement from the Royal Victoria Hospital (RVH) which administers the AMI, while another, Dr. Mary Morrow, a psychiatrist, is resuming a $1.5 million suit against the RVH in the Quebec Court of Appeals.[9] Furthermore, documents made public in 1977 have led nine of Dr. Cameron's former patients to collectively sue the United States government for $9 million for impaired health and personal injury.

It is doubtful that Dr. Cameron's good reputation as a psychiatrist would have been tarnished by this research if he had fulfilled the requirements for informed consent. This requirement is best derived from the ethical principle of respect for persons which was formally stated by Immanuel Kant: "So act as to treat humanity, whether in their own person or in that of any other, in every case as an end withal, never as a means only."[10] For Hans Jonas[11] and Paul Ramsey[12], the use of persons as means to another's end, as in research, is justified only if they so identify with the purposes of research that they "will" them as their own. The consent requirement affirms a basic covenantal bond between subject and researcher, and ensures that the person is not used simply as a means to an end. Jones and Ramsay also argue that to establish a proper covenant, the subject's consent must be informed; that is, it must reflect a genuine appreciation of the purposes and especially of the risks of the research. The less one understands the risks and the less one identifies with the purposes of research, the less valid is one's consent and the less desirable one's participation.

Although some may argue that Cameron was merely invoking the legal doctrine of therapeutic privilege, according to which a physician may withhold information when in his or her judgement, disclosure is either not feasible or potentially harmful, others would mention with validity the negative aspects of such privilege. Such critics argue that invoking the doctrine of therapeutic privilege to justify withholding of information from a prospective subject to assure co-operation in a research project is almost never appropriate. It gives the researcher entirely too much licence to serve his own interests by withholding information that might be material to the decision of a prospective subject.[13]

Is it likely that a scientist could conduct research with humans today in a manner such as that of the late 1950s? The answer is probably not, for today if patients are asked to submit to drug treatment or other forms of therapy that may be somewhat "new", they must be fully informed of what it involves. Furthermore, an ethics committee must examine all the possible ramifications of such treatment before its use is authorized. I see this to be our safest means of ensuring the ethical use of persons in scientific experimentation and research.

However, given the human potential for abuse, it is not impossible that in the future, ethics committees might become instruments, unintended and unexpected at present, of blocking desirable, necessary and innovative research on philosophical grounds which have nothing to do with ethics. Thus, one or more members of an ethics committee may be opposed to a new direction of research and they might then utilize their position to block such research. Consideration should be given to safeguarding the work of ethics committees from such abuse. After all, was Socrates not found guilty of poisoning the minds of youth by an "ethics committee" of his time?

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